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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,935		JACQUES DUMAS	BAYER 12P1	7400

7590

11/15/2001

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EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 11/15/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/776,935

Applicant(s)

DUMAS, JACQUES

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 September 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **Detailed Action**

Applicant's response to the specie election requirement submitted September 7, 2001 (Paper No. 6) is acknowledged.

Applicant's election with traverse therein of the compound shown in example 21 and the disease of rheumatoid arthritis in Paper No. 6 submitted September 7, 2001 is acknowledged.

The specie election of August 1, 2001 is based on the diverse classification of the specie encompassed by the claims, see particularly pages 3 and 4 of the specie election requirement. As shown in the restriction requirement of August 1, 2001 the compounds encompassed by the claims fall into different subclasses of class 514, e.g., 307, 311, 407, 241, 447, 431, 444, 411, 454, 461, etc. The search for all possible compounds is therefore an undue burden on the office. Note that the search is not limited to patent files.

**Since the elected compound specie recited was found to be free of the prior art, the search has been extended to compounds 1, 3-5, 8, 10, 13-16 of table 1 (2-substituted-5-tert-butylpyrazolyl ureas).**

Applicants also traverse the specie election of the disorders and diseases on the ground that all of the enumerated disorders involve diseases mediated by p38 which is inhibited by the claimed method. Applicant's arguments have been considered but are found unpersuasive because the treatment for each p38 mediated disease represents a separate field of medical technology, see the election of species requirement of August 1, 2001, see particularly page 2.

Applicant's remarks regarding related application 09/425,299 have been considered but are not persuasive. Note that patents and patent applications do not constitute legal precedence.

Because the considerations as to patentability are individual to each Group herein and the burden of search for all inventions and species is undue, as discussed herein and in the restriction requirement, the restriction requirement is maintained.

The requirement is still deemed proper and is therefore made FINAL.

**Claims 1-16 are herein examined on the merits in so far as they read on compounds 1, 3-5, 8, 10, 13-16 of table 1 (2-substituted-5-tert-butylpyrazolyl ureas and the elected disorder of rheumatoid arthritis.**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The description of moiety A is incomprehensible because lines 1-11 of claim 1 read as follows: "wherein A is a heteroaryl selected from the group consisting of wherein R1 is selected from the group...." The definition of moiety A is therefore incomprehensible.

In order to expedite prosecution, the three heterocyclic formulas have been taken to be between lines 10 and 11 of claim 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Regan et al. (USPN 6,080,763).

Regan et al. (USPN 6,080,763) teaches a method of treating inflammatory disorders including the elected specie, rheumatoid arthritis, employing compounds of formula I (compounds of formula I encompass compounds 1, 3-5, 8, 10, 13-16 of table 1 (2-substituted-5-tert-butylpyrazolyl ureas) see cols. 6-19, see also claims 1-8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any of the compounds of formula I in a method of treating rheumatoid arthritis.

One of ordinary skill in the art would have been motivated to employ compounds 1, 3-5, 8, 10, 13-16 of table 1 (2-substituted-5-tert-butylpyrazolyl ureas) specifically in a method of treating rheumatoid arthritis because these compounds are known in the prior art to be useful in treating inflammatory diseases in general, and rheumatoid arthritis specifically.

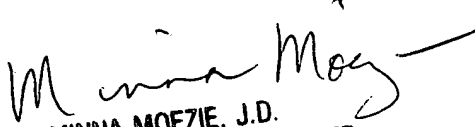
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
November 9, 2001

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600